

DOCKET NO.: 283035US0PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Beth E. DREES, et al.

SERIAL NO.: NEW U.S. PCT APPLICATION

FILED: HEREWITH

INTERNATIONAL APPLICATION NO.: PCT/US04/18752

INTERNATIONAL FILING DATE: June 14, 2004

FOR: COMPOUNDS HAVING INHIBITIVE ACTIVITY OF PHOSPHATIDYLINOSITOL 3-KINASE AND METHODS OF USE THEREOF

**REQUEST FOR CONSIDERATION OF DOCUMENTS
CITED IN INTERNATIONAL SEARCH REPORT**

Commissioner for Patents
Alexandria, Virginia 22313

Sir:

In the matter of the above-identified application for patent, notice is hereby given that applicant(s) request that the Examiner consider the documents cited in the International Search Report according to MPEP §609 and so indicate by a statement in the first Office Action that the information has been considered. When the Form PCT/DO/EO/903 indicates both the search report and copies of the documents are present in the national stage file, there is no requirement for the applicant(s) to submit them (1156 O.G. 91 November 23, 1993).

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Norman F. Oblon
Attorney of Record
Registration No. 24,618
Surinder Sachar
Registration No. 34,423

Customer Number
22850

(703) 413-3000
Fax No. (703) 413-2220
(OSMMN 08/03)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 21780.PROV.PCT	FOR FURTHER ACTION	See Form PCT/IPBA/416																								
International application No. PCT/US04/18752	International filing date (day/month/year) 14 June 2004 (14.06.2004)	Priority date (day/month/year) 13 June 2003 (13.06.2003)																								
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/4745, 31/437, 29/00, 35/00, 37/00; C07D 471/04 and US Cl.: 514/293, 303; 546/82, 119, 120																										
Applicant ECHELON BIOSCIENCES INCORPORATED																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																										
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 13 January 2005 (13.01.2005)	Date of completion of this report 22 September 2005 (22.09.2005)																									
Name and mailing address of the IPBA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	<div style="text-align: center;"> Authorized officer Bernard Deryz Telephone No. 571 272-1600 </div>																									

Form PCT/IPBA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/18752

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-49 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the claims:
- pages 50-55 as originally filed/furnished
- pages* NONE as amended (together with any statement) under Article 19
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ the drawings:
- pages NONE as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

Form PCT/IPEA/409 (Box No. I) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/18752

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
 - ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest, and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ neither restricted the claims nor paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
 - ☐ complied with.
 - ☒ not complied with for the following reasons:

Group I, claim(s) 4-8 and 9-19 in part, drawn to a compound of formula I, the composition and method of use thereof.

Group II, claim(s) 1-3, 9-19 in part, drawn to a compound of formula II, the composition and method of use thereof.

Group III, claim(s) 1-3, 9-19, drawn to a compound of formula III, the composition and method of use thereof.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The Group I tricyclic compound of formula I, the Group II bicyclic compound of formula II with a carbonyl substituent and the group III bicyclic compound with an oxo substituent would not have been of sufficient similarity to allow a Markush grouping exhibiting unity, absent some teaching of equivalence in the prior art.
4. Consequently, this report has been established in respect of the following parts of the international application:
 - ☒ all parts
 - ☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/18752**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>8 and 15-17</u>	YES
	Claims <u>1-7, 9-14, 18, 19</u>	NO
Inventive Step (IS)	Claims <u>8, 15-17</u>	YES
	Claims <u>1-7, 9-14, 18, 19</u>	NO
Industrial Applicability (IA)	Claims <u>1-19</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-7, 9-14, 18 and 19 lack novelty under PCT Article 33(2) as being anticipated by US 3,935,222. The compounds of Ex. 1-20, the pharmaceutical composition and the method for treating inflammation are encompassed by the instant wherein the compound is of formula III.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Quiroga et al (Tetrahedron, (2001), 57, 6947-6953). the compounds 4a-4h, 4j-4l (page 6947, Scheme 1) are encompassed by the instant wherein the compound is of formula I.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Ohki et al. The compound described in the abstract is encompassed by the compound of formula III.

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Quiroga et al (J. of Heterocyclic Chem. , (1998), 35(2), 409-412). The compounds in the abstract are encompassed by the instant wherein the compound is of formula III.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Weissfels et al (Zeitschrift fuer Chemie, (1981), 21(7), 259-260. The compounds described in the abstract are encompassed by the instant wherein the compound is of formula III.

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Weissenfels et al (Zeitschrift fuer Chemie, (1982), 22(1), 23-24). The compound described in the abstract is encompassed by the instant wherein the compound is of formula III.

Claims 8 and 15-17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instant compounds having the recited substituents on R1-R5, or the method of using the inventive compound for inhibiting the growth of cancer cells.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus possess industrial applicability because the subject matter claimed can be made or used in industry.